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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,861	02/24/2004	Thomas P. Hedman	89188.0058	3669
26021 7590 01/22/2008 HOGAN & HARTSON L.L.P. 1999 AVENUE OF THE STARS SUITE 1400 LOS ANGELES, CA 90067			EXAMINER OLSON, ERIC	
			ART UNIT 1623	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/786,861	Applicant(s) HEDMAN, THOMAS P.	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 is/are allowed.
- 6) ☒ Claim(s) 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

This office action is a response to applicant's communication submitted November 15, 2007 wherein claims 1 and 2 are amended and claims 10-18 and 22-30 are cancelled. This application claims benefit of provisional application 60/498790, filed August 28, 2003, and is a continuation in part of application 10/230671, now pending, filed August 29, 2002, which claims benefit of provisional application August 29, 2002.

Claims 1-9 and 19-21 are pending in this application.

Claims 1-9 and 19-21 as amended are examined on the merits herein.

The terminal disclaimer filed on November 15, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on pending patent application 11/346464 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's amendment, submitted November 15, 2007, with respect to the objection to claims 1-9 and 19-21 for reciting the nonsensical phrase, "invertebrate disks," has been fully considered and found to be persuasive to remove the objection as the phrase has been corrected to recite intervertebral disks. Therefore the objection is withdrawn.

Applicant's amendment, submitted November 15, 2007, with respect to the rejection of instant claims 10, 11, 15, and 22-24 under 35 USC 102(b) for being

anticipated by Kondo et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 15, 2007, with respect to the rejection of instant claims 10, 11, 15, and 22-24 under 35 USC 102(b) for being anticipated by Chang et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 15, 2007, with respect to the objection to instant claims 10, 11, 13, 15, and 22-24 under 35 USC 102(b) for being anticipated by Murad, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 15, 2007, with respect to the rejection of instant claims 12, 14, 17, 18, 25, and 27-30 under 35 USC 103(a) for being obvious over Kondo et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 15, 2007, with respect to the rejection of instant claims 12, 14, 17, 18, 25, and 27-30 under 35 USC 103(a) for being obvious over Chang, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted November 15, 2007, with respect to the rejection of instant claims 16-18 and 26-30 under 35 USC 103(a) for being obvious over Murad in view of Ng et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's terminal disclaimer, submitted November 15, 2007, with respect to the rejection of instant claims 19-21 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 1-3, 5-10, 14-16, 18-21, 25-27, and 29-35 of copending Application No. 11/346464, has been fully considered and found to be persuasive to remove the rejection as the terminal disclaimer is proper. Therefore the rejection is withdrawn.

### ***Priority***

The US parent application 10/230671, filed August 29, 2002 and the provisional applications 60/498790, filed August 28, 2003, and 60/316287, filed August 31, 2001,

upon which priority is claimed fail to provide adequate support under 35 USC 112, first paragraph for the claimed subject matter of instant claims 1-9 and 19-21 of this application because these applications are not seen to disclose any methods of treating scoliotic spines according to instant claims 1-9 or of increasing permeability or cell viability of intervertebral discs according to instant claims 19-21. Thus, the filing date of the instant claims is deemed to be the filing date of the instant application, February 24, 2004.

The following new grounds of rejection are introduced:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Slivka et al. (US patent 6812211, cited in PTO-892) Slivka et al. discloses a method of treating a pathological intervertebral disc wherein a crosslinking agent is administered to the disc in an amount sufficient to crosslink at least a portion of the proteins present in the disc. (column 3, lines 35-50) The crosslinking agent affects the nucleus pulposus, (column 4, lines 5-14) which is a collagenous tissue, and the proteins being crosslinked

inherently include collagen. Furthermore, the therapeutic effects, concerning the increased permeability and fluid flux of the affected discs, and increased viability of cells in the central region of the intervertebral disc, are considered to be inherent properties of the method of introducing a crosslinking agent into the intervertebral disc, and do not serve to distinguish the claimed invention over the prior art. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F.3d 955, 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein.

Therefore the claimed invention is anticipated by Slivka et al.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-29 of copending Application No. 10/230671. (published as PG pub 2003/0049301, cited in PTO-892, herein referred to as '671) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 24-29 of '671 anticipate the claimed invention. Specifically, these claims recite a method whereby a crosslinking agent is introduced into a nucleus pulposus. The nucleus pulposus is a collagenous tissue, and the proteins being crosslinked inherently include collagen. Furthermore, the therapeutic effects, concerning the increased permeability and fluid flux of the affected discs, and increased viability of cells in the central region of the intervertebral disc, are considered to be inherent properties of the method of introducing a crosslinking agent into the intervertebral disc, and do not serve to distinguish the claimed invention over the prior art. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. Therefore the claimed invention is anticipated by claims 24-29 of '464.



This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

Claims 19-21 are rejected. Claims 1-9 are seen to be allowable. Reasons for the indication of allowable subject matter are given below:

The claimed invention is seen to be adequately described and enabled by the specification. For example, the treatment of scoliotic spines according to the invention is disclosed on pp. 8-9 of the specification. The examples on pp. 20-29 demonstrate that the claimed treatment increases the stiffness and resistance to bending of the affected spine, parameters that would be expected to reduce or treat scoliosis. Therefore the claimed invention meets the requirements of 35 USC 112.

The claimed invention is also seen to be novel and non-obvious over the prior art. Although certain prior art references such as Slivka et al. are seen to teach a method comprising injecting a crosslinking agent into an intervertebral disk, The prior art does not disclose a method wherein this treatment is specifically practiced on a scoliotic spine. Furthermore, the state of the art for treating scoliosis involves physical reinforcement of the spine such as bracing or spinal fusion. One of ordinary skill in the art would not have considered a method of crosslinking the intervertebral disk to be obviously useful for treating scoliosis. Therefore the claimed invention is seen to be novel and non-obvious over the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner  
AU 1623  
1/16/08

Anna Jiang



Supervisory Patent Examiner  
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